K111761

JAN 1 0 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: October 16, 2011

1. Company and Correspondent making the submission:

	Company
Name	neobiotech Co., Ltd.
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Contact	Shin, Seon Woo

2. Device:

Proprietary Name – Neo Titanium mesh, CTi-mem
Common Name – Titanium Ridge Augmentation Mesh
Classification Name – Bone Plate

3. Predicate Device:

Osteo-Mesh TM-300, K984230, Osteogenics Biomedical

4. Device Classification:

JEY, CFR872.4760, Class 2

5. Device Description:

The Neo Titanium mesh and CTi-mem are meshes and membranes intended to be used for stabilizing and supporting bone grafts in dento-alveolar bony defect sites. The devices are fabricated from Grade 2 Titanium (ASTM F-67) and supplied in various sizes and shapes, non-coated, sterile, for single-use and disposable.

The membranes are shaped and/or trimmed by the user for the intended target shape. The Neo Titanium mesh is the common shape of the membrane. The Cti-mem series are customized titanium membranes allowing minimum cutting and bending for attaching to the location of the part used.

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6. Indication for use:

For stabilization and support of bone grafts in dento-alveolar bony defect sites.

7. Non-Clinical Performance Testing:

Performance testing conducted included visual, dimension, packaging, and package seal efficacy testing.

The biocompatibility of Titanium has been established through a long history of use in implantable medical devices. No additional biocompatibility testing was necessary for this device.

8. Comparison to Predicate Devices:

The Neo Titanium mesh and CTi-mem have the same device characteristics, composition, function, and intended use as the predicate device, such as the Osteo-Mesh TM-300.

The differences between the devices are material thickness, dimensions, hole size and method of sterilization.

Based on the comparison of intended use and technical features, the Neo Titanium mesh and CTi-mem are substantially equivalent to the predicate device.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification neobiotech Co., Ltd. concludes that the Neo Titanium mesh and CTi-mem are safe and effective, perform at least as well, and are substantially equivalent to the predicate devices as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neobiotech Company, Limited
C/O Mr. Ronald Arkin
President
Arkin Consulting Group
1733 Canton Lane
Marietta, Georgia 30006

JAN 10 2012

Re: K111761
Trade/Device Name: Neo Titanium mesh, CTi-mem
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: January 4, 2012
Received: January 6, 2012

Dear Mr. Arkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

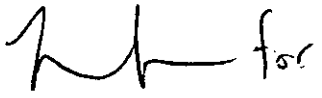
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 111761

Device Name: Neo Titanium mesh, CTi-mem

Indication for use:

For stabilization and support of bone grafts in dento-alveolar bony defect sites.

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111761